Statement of Consumers Union

FDA Public Hearing on Promotion of Medical Products via the Internet and Social Media
(Question 2 – Challenges the Web presents)

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Good morning and thank you for the opportunity to comment today.

I am speaking on behalf of Consumers Union. CU is the independent, non-profit publisher of *Consumer Reports* magazine, *ConsumerReports.org*, and *ConsumerReportsHealth.org.*[1] These Web sites contain information on prescription drugs. We also lobby on health care issues and I am a registered lobbyist.

[1] Consumers Union, nonprofit publisher of *Consumer Reports*, is an expert, independent organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. To achieve this mission, we test, inform, and protect. To maintain our independence and impartiality, Consumers Union accepts no outside advertising, no free test samples, and has no agenda other than the interests of consumers. Consumers Union supports itself through the sale of our information products and services, individual contributions, and a few noncommercial grants.

My comments today are confined to question 2. Yes, indeed, the Web is a different beast than print publications or TV. It has presented new and terrific opportunities to communicate with the public about the benefits, risks and appropriate, safe use of prescription drugs and other medical products. It also poses regulatory dilemmas, just as DTC advertising did in the 1990s.

More recently, the advent of smart phones, ever-ready internet, digital media, new means of person-to-person communication (Text, Twitter, etc), and the Internet's evolution to become a vast social networking medium have all posed new questions about how drug information and promotion is shared.

I'd like to make seven points:

(1) What happened with DTC ads should be a cautionary tale. The 1997 "clarification" from FDA on broadcast ads for drugs gave birth to a new era of pharmaceutical marketing that has had broad and unintended effects. A genie was let out of the bottle. In our view, FDA must proceed carefully to prevent a similar result as it ponders how to guide and regulate drug and device information on the Web and via digital media.

(2) On Web sites, the solution to the question at hand is simple. All the existing regulations that apply to print should apply to the Web – and then some. Space is not a restriction on the Web as compared to a magazine or newspaper or a TV screen during a 30 second ad, and thus full "fair and balanced" information on the recommended use, benefits, and potential risks, side effects and adverse events should be required in the context of any "educational" or promotional material from companies. As for "packaging," presentation, and layering of information, we believe regulations should require companies to present risk and cautionary information on Web sites with EQUAL PROMINENCE to benefit information. The Web involves design

issues similar to TV. You attract people's attention with graphic display, music and increasingly with video. We believe updated regulations pertaining to the Web should prevent the layering of information that, in practice, buries risk information. All Web mavens know that the drop off of viewing occurs progressively the more clicks required. It should not be permissible to have a drug promotion Web site that displays all the "good stuff" on the home page and requires a click through to any critical risk or side effect information.

(3) We would also support regulations that require a direct link to FDA's online content on a product or drug or device for any Web site that is owned by or substantially supported with funds from the manufacturer of that drug or device. The link would have to be displayed prominently in an appropriate place. This measure should not, however, negate the requirement of companies to have such information on their own site.

(4) Drug information and tools ("apps") designed for smart phones, reading devices or other digital hardware should have to abide by the same rules as for the Web. All risk information must be present. A well designed app is just as flexible as the Web, just in different ways. There is no space limitation. And that environment, as it now exists, allows design with more "screen touches" without losing eyeballs.

(5) Email, text messaging and social networking sites pose different challenges. We don't believe drug or device companies should be engaged <u>in any promotion of their products</u> via direct email or text messaging to consumers, blast email or email list-serves, chat rooms, or social networking bulletin boards that are operated by third parties. Period. The only legitimate use of such tools to communicate directly with consumers is via a company's own Web sites. And in that case, we believe full "fair and balanced" information rules should apply.

(6) While the agency is thinking about all this, we urge you formally investigate the use of Web promotion by companies via sponsored links on search engines, Google and others. Along with that should be an examination of company's use of search engine optimization. It's no secret (it's discussed openly in the drug trade literature) that pharmaceutical companies are pouring significant resources into looking at these tools to promote their products. We believe it's incumbent on the FDA to understand these techniques better and quantify their impact on public health and the safe use of medicines.

(7) Lastly, we believe FDA will need more resources to do this job. That money should, for now, come from industry user fees. We will be advocating this in the context of the PDUFA 5 negotiations which begin next year.

Thanks you for the opportunity to comment today.